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ATTACHMENT H

SMDA REQUIREMENTS

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Sterile Water and Saline Bottles for Irrigation, USP

Manufacturer:	Automatic Liquid Packaging, Inc. 2200 Lake Shore Drive Woodstock, IL 60098
Regulatory Affairs Contact:	John Brda
Telephone:	815/338-9500
Sponsor:	Barry L. Farris Avitro LLC 276 Kingsbury Grade – suite 104 Zephyr Cove, NV 89448 Phone: 775/588-6899
Date Summary Prepared:	February, 2000
Common Name:	0.9% Sodium Chloride Vascular Access Flush Device
Classification:	Class II per 21CFR & 868.5860
Predicate Device	0.9% Sodium Chloride Vascular Access Flush Device
Description:	The only ingredient in the solution other than water is Sodium Chloride; there are no preservatives or stabilizers. The container is manufactured of 100% low-density polyethylene (LDPE) and contains no color or chemical additives. The solution is sterile, aseptically filled and is hermetically sealed for single use only.
Intended Use:	0.9% Sodium Chloride Vascular Access Flush Device is defined as an accessory to a device that is intended for use to maintain patency of an indwelling intravenous Access Flush Device. (IVAD).

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SMDA REQUIREMENTS CONTINUED

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Sterile Water and Saline Bottles for Irrigation, USP

Substantial Equivalence:

The Avitro LLC, 0.9% Sodium Chloride Vascular Access Flush Device Solution is substantially equivalent to the Vital Signs Sodium Chloride Vascular Access Flush Device Solution in that:

- The intended use is the same
- The performance attributes are the same

Summary of testing:

All materials used in the fabrication of Avitro 0.9% Sodium Chloride Vascular Access Flush Device Solution were evaluated through biological qualification safety tests as outlines in ISO 10993 Part-1 "Biological Evaluation of Medical Devices." These material also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2000

Avitro LLC
C/O Mr. John Brda
Regulatory Affairs Manager
Automatic Liquid Packaging, Incorporated
2200 Lake Shore Drive
Woodstock, Illinois 60098-7498

Re: K000632
Trade Name: 0.9% Sodium Chloride Vascular Access Flush Device
Regulatory Class: II
Product Code: FOZ
Dated: September 18, 2000
Received: September 20, 2000

Dear Mr. Brda:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000632

ATTACHMENT C

510(K) Number (if known)	Unknown
Device Name:	0.9% Sodium Chloride Vascular Access Flush Device
Indications for Use:	0.9% Sodium Chloride Vascular Access Flush Device as defined for use to maintain patency of indwelling Intravenous Access Device (IVAD).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K000632